

**November 29, 1999**  
**FACT SHEET**

**Rule Suspension for Specified Ethylene Oxide Sterilization and Fumigation Operations**

**TODAY'S ACTION**

- The Environmental Protection Agency (EPA) is suspending its final air toxics rule requirements for ethylene oxide commercial sterilization and fumigation operations for chamber exhaust and aeration room vents. These operations sterilize medical equipment and equipment supplies, as well as fumigate food.
- The suspension allows facilities subject to the final rule to defer compliance with the requirements for chamber exhaust and aeration room vents for until December 6, 2001 and December 6, 2000, respectively.
- This suspension does not affect facilities subject to sterilizer vent requirements with a December 6, 1998 compliance date. This is because safety problems were determined to be associated only with chamber exhaust and aeration room vent emission control.

**HISTORY**

- The ethylene oxide rule for commercial sterilizers was finalized in November 1994. Under the Clean Air Act of 1990, affected facilities had up to three years to comply with this regulation.
- In July 1997, EPA learned of explosions at certain ethylene oxide sterilization and fumigation facilities. EPA subsequently suspended the ethylene oxide rule for one year until December 6, 1998 to provide time to determine the appropriate action necessary to mitigate the cause of the explosions.
- A wide array of parties, including EPA, the Ethylene Oxide Sterilization Association (EOSA), the Health Industry Manufacturers Association, company representatives, and vendor representatives investigated the cause(s) of the explosions. In June 1998 EOSA recommended further delay to correct unsafe operating conditions. All stakeholders agreed with the decision.
- On August, 3, 1998, EPA informed the EOSA of EPA's intent to further delay the aeration and chamber exhaust vent requirements. These requirements were suspended until December 6, 1999.
- The EOSA safety subcommittee informed EPA in a June 1999 letter that safety issues had not been developed and were unlikely to be resolved in time to meet the December 6, 1999 compliance date for aeration and chamber exhaust vents. Additionally, the EOSA requested the chamber exhaust vent not be regulated.

**FOR FURTHER INFORMATION**

- Interested parties can download the suspension notice from EPA's World Wide Web site at <http://www.epa.gov/ttn/oarpg/ramain.html>. For questions concerning the rule suspension, contact your EPA Regional Office, or David Markwordt of EPA's Office of Air Quality Planning and Standards at (919) 541-0837.